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**STUDIES HIGHLIGHT SHORTCOMINGS OF  
AIDS TREATMENTS**

- Only One-Third of Patients Receive Long-Term Suppression of HIV from Combination Therapy –**
- Studies Find Sharp Disparities in HAART Prescription and Use by Race and Gender -**
- Pilot Programs in Developing Countries Show Drug Efficacy, but High Levels of Viral Resistance Found –**

*DURBAN, South Africa* – New studies from the U.S. Centers for Disease Control and Prevention (CDC) discussed today highlight the growing shortcomings of existing treatment regimens. The studies were discussed at a press briefing held by CDC at the XIII International AIDS Conference.

One study discussed today suggests that only one-third of U.S. patients may receive long-term suppression of HIV from highly active antiretroviral therapy (HAART), and that those patients who have changed HAART regimens in the course of AIDS treatment are less likely to experience long-term viral suppression.

Other CDC studies revealed continued racial and gender disparities in access to the most effective therapies, and examined the contributing role stress may play in poor adherence among women. In one study, women and African Americans were less likely to be prescribed HAART than white men. Another study found that women, particularly women who were depressed or dealing with issues such as job loss, family illness, and other stressful events, were less able to adhere to HAART regimens, which cost as much as \$15,000 a year and demand that patients adhere to complicated dietary and time restrictions.

“All of these studies underscore the importance of distinguishing between the hope for a ‘magic bullet’ against AIDS and the reality of existing treatments,” said Helene D. Gayle, M.D., M.P.H., Director of CDC’s National Center for HIV, STD, and TB Prevention. “While we clearly need new treatment options and a better understanding of how to combat viral resistance, these studies remind us that HIV prevention is still our best hope – both in the United States and throughout the world, especially here in Africa.”

CDC studies conducted in Uganda and Côte d’Ivoire, also presented today, reveal that while expanding access to HAART remains critical, issues of resistance and adherence also pose significant challenges. Patients in developing nations were found to have extremely high levels of viral resistance to the drugs and potential problems in adhering to the complicated regimens. These studies are among the first to evaluate pilot programs providing HAART in the developing world.

## **KEY U.S. FINDINGS**

### **HAART: Working, But For How Long and For Whom?**

CDC presented a number of studies highlighting growing concern about existing AIDS treatments. Some studies raised questions about the long-term efficacy of HAART, while others highlighted disparities in the prescription of the regimens and problems with their use.

“Patients are struggling – to get on these regimens, to stay on them once prescribed, and to benefit from them over the long-term,” said CDC researcher Scott Holmberg, M.D., author of several studies and a presenter at the briefing. “We will need strategies to assist HIV-infected men and women with adherence, and we will need more drug options, since those we have are increasingly being exhausted by the people who need them.”

HAART involves a combination of three or more AIDS drugs, including two of the drugs known as nucleoside analog reverse transcriptase inhibitors (NARTIs), as well as one or more protease inhibitors or non-nucleoside analog reverse transcriptase inhibitors (NNRTIs).

- **Patients Forced to Change Regimens with Increasing Frequency:** HAART continues to be effective, according to data presented by Holmberg, but patients are having to change drugs and regimens increasingly often to maintain those benefits. Holmberg’s study, which analyzed medical data from more than 1,600 U.S. AIDS patients nationwide, found that HAART use had climbed from below 4 percent at the end of 1995 to 87 percent in the third quarter of 1999. Corresponding declines were noted in both rates of AIDS deaths – which fell by 93 percent from 1994 to 1999 among patients studied – and in rates of opportunistic infections, which on average declined by 87 percent in the same period.

On average, patients stayed on their first course of HAART for only 10.6 months before the treatment proved ineffective or intolerable; those on their second course of HAART remained on that regimen for only 8.1 months; and those on a third course of HAART remained on it for 6.4 months. [*Abstract ThOrC723, “Continued Low Morbidity and Mortality Among Patients with Advanced HIV Infection and Their Patterns of Highly Active Antiretroviral Therapy (HAART) Usage,” Scott Holmberg, M.D., Oral Presentation, Thursday, 13 July 2000, 15:30 (9:30 AM EDT)*]

- **Virus Suppressed Long-term in Only About One-third of HAART Patients:**  
Significant questions about the long-term efficacy of HAART also were raised by Holmberg's data, which showed that the combination therapies successfully suppressed the virus for twelve months or more in only approximately one-third (36%) of patients who were observed for at least 15 months. Patients were more likely to achieve long-term treatment success with first HAART (49 percent), than with second HAART (30 percent), or third or more HAART (15 percent). This analysis, completed on a subset of 366 patients from the larger study (above), found that factors associated with increased likelihood of treatment success included never having taken antiretroviral therapy prior to beginning HAART, and receiving HAART with a single protease inhibitor (especially indinavir or nelfinavir), rather than receiving HAART with two protease inhibitors (especially saquinavir or ritonavir). [*Abstract TuPpB1166, "Correlates of Durable Treatment Success among Long-Term Highly Active Antiretroviral Therapy (HAART) Recipients in the HIV Outpatient Study (HOPS)," Scott Holmberg, M.D., Oral Poster Presentation, Tuesday, 11 July 2000, 11:30 (5:30 AM EDT)*]
- **Treatment Disparities by Race and Gender:** Women and African Americans may be less likely to be prescribed HAART than men and whites, according to another study presented today. The study, by CDC researcher A.D. McNaghten, followed 9,113 patients in 11 U.S. cities to assess prescription patterns for HIV antiretroviral therapy among those eligible for such treatment under recommended guidelines. More than 80 percent of eligible patients were prescribed some type of antiretroviral therapy; 56 percent were prescribed HAART; and 18 percent were not prescribed any antiretroviral therapy. Women in the study were 24 percent less likely than men, and African Americans were 12 percent less likely than whites, to be prescribed HAART. The inequities found require further study to determine if certain factors (including health coverage or health care providers' perceptions of which groups are more likely to adhere to HAART regimens) affect the likelihood of HAART prescription for these populations. (*Abstract ThPeB5286, "Inequities Between Gender and Racial*

***Groups in Prescription of Highly Active Antiretroviral Therapy,” A.D. McNaghten, Poster Presentation, Thursday, 13 July 2000, 11:15 (5:15 AM EDT)]***

- **Once Prescribed, Initial HAART Therapy More Likely to Fail for Women:**

Among patients new to HAART, women were less likely than men to develop the level of viral suppression that defines treatment success, according to a CDC study discussed today. A study of 76 patients who were prescribed HAART for the first time at an inner-city clinic in the Southeastern United States, led by CDC researcher Linda Koenig, found that women were significantly more likely to experience treatment failure within the first five months of HAART than men. Almost 30 percent of women failed to show a significant decrease in viral load after initiating treatment. Women who failed therapy reported more depression, more perceived stress, less social support, and more misconceptions about HAART, compared to men and women whose therapy was successful. A small number of men (10 percent) also failed HAART, but more research is needed to better understand the factors associated with failure. In the study, age, race, income, and history of crack cocaine or injection drug use were not associated with treatment failure. *[Abstract WePeB4148, “Predictors of Early Failure of Highly Active Antiretroviral Therapy (HAART),” Linda Koenig, Poster Presentation, Wednesday, 12 July 2000, 11:15 (5:15 AM EDT)]*

Another study, which focused specifically on HIV-infected women and their ability to adhere to antiretroviral therapy, also found that recent illicit drug use, race and income had no bearing on adherence. This study, of 520 HIV-infected women eligible for antiretroviral therapy in four U.S. cities, was conducted by CDC researcher Jan Moore, and found that only 288 (55 percent) were taking any antiretroviral medication. An estimated 26 percent of women taking HIV medication were unable to adhere completely to their treatment regimens. Depression, HIV-related stress, and adverse events such as loss of income or family illness, were

associated with failure to adhere fully to HIV treatment regimens. *[Abstract WePeD4598, “Predictors of Adherence to Antiretroviral Therapy Among HIV-infected Women,” Jan Moore, Poster Presentation, Wednesday, 12 July 2000, 11:15 (5:15 AM EDT)]*

## **KEY INTERNATIONAL FINDINGS**

### **Combination AIDS Therapy – and Viral Resistance – in the Developing World**

There has been little study of the effectiveness of HAART on viral strains prevalent in sub-Saharan Africa, which is home to more than 23 million adults and children living with HIV and AIDS. A new CDC study finds that HAART is proving to be more effective than two-drug therapy alone for patients in the UNAIDS drug access pilot programs in Uganda and Côte d’Ivoire. These findings are consistent with studies in the United States and Europe. Yet, several CDC studies highlight the problem posed by viral resistance in the drug access initiatives.

“As the use of antiretroviral therapy in Africa and other parts of the developing world increases, it will be essential to monitor viral resistance and learn more about patient adherence to medications,” said Gayle. “Clearly, cost and access are not the only barriers to effective care.”

A separate study found that women in Côte d’Ivoire might require AIDS therapy earlier than men, due to newly identified differences between men and women in the relationship between viral load and CD4+ immune cell counts.

### **HAART Better than Two-drug Therapy in Africa**

- **Uganda:** In a 20-month program evaluation of patients in the Ugandan UNAIDS HIV Drug Access Initiative begun in 1998, patients who remained on HAART for more than one year experienced greater benefit than those on a regimen which only

included two nucleoside analog reverse transcriptase inhibitors (NARTIs). The observational evaluation, led by CDC researcher Paul Weidle, M.D., found that among patients on the two NARTI regimen, both their CD4 counts (a measure of immune suppression) and their viral load had almost returned to baseline levels one year after initiation of therapy. People on HAART, however, continued to experience substantial improvements, by both measures, after one year of therapy. Although less expensive than HAART, dual NARTI therapy is still costly to patients and has a less durable benefit. In Uganda, lowering the costs of protease inhibitors and NNRTIs could help ensure that patients benefit from optimal treatment strategies. [*Abstract ThPeB5231, “Evaluation of Patients Accessing Antiretroviral Therapy in the UNAIDS HIV Drug Access Initiative in Uganda,” Paul J. Weidle, M.D., Poster Presentation, Thursday, 13 July 2000, 11:15 (5:15 AM EDT)*]

- **Côte d’Ivoire:** In Abidjan, Côte d’Ivoire, patients on HAART also received greater benefit than those on a two-drug regimen. The study, of 422 previously untreated patients in the UNAIDS/Ministry of Health drug access initiative in Abidjan, found that patients on HAART received a more pronounced and sustained virologic response than patients on two NARTIs. After 300 days of therapy, 17 percent of those on NARTIs achieved undetectable viral load levels, compared to 38 percent on HAART. [*Abstract TuOrB295, “Virologic and Immunologic Response to Antiretroviral Therapy among Patients Participating in the UNAIDS/Ministry of Health Initiative to Improve Access to Therapy for HIV-infected Persons in Côte d’Ivoire,” Gaston Djomand, M.D., Oral Presentation by Madeleine Sassan-Morokro, M.D., Tuesday, 11 July 2000, 13:15 (7:15 AM EDT)*]

### **High Levels of Resistance Found**

- **Uganda:** While HAART was found to be effective against HIV, high levels of resistance were documented in the UNAIDS drug access initiative in Uganda, according to the lead study author, Paul Weidle, M.D. After testing blood drawn from a subsample of 30 patients in the program, Weidle and colleagues found that

phenotypic resistance<sup>1</sup> to at least one AIDS drug was present in 74 percent of the samples. Resistance was highest to lamivudine (3TC), with 78 percent of patients taking the drug exhibiting some signs of resistance. By comparison, 20 percent of specimens from patients on zidovudine (AZT) demonstrated resistance. Because of the high level of 3TC resistance found in this setting, which has also been documented in North America and Europe, Weidle's findings suggest that 3TC should only be used in Uganda as part of a maximally suppressive regimen to decrease the development of resistance. [*Abstract TuPeB3293, "Development of Phenotypic and Genotypic Resistance to Antiretroviral Therapy in the UNAIDS HIV Drug Access Initiative – Uganda," Paul J. Weidle, M.D., Poster Presentation, Tuesday, 11 July 2000, 11:15 (5:15 AM EDT)*]

- **Côte d'Ivoire:** CDC also documented high rates of antiretroviral drug resistance among patients with a history of antiretroviral therapy seeking care in the UNAIDS initiative in Abidjan, Côte d'Ivoire. The study, by CDC researcher Christiane Adje, tested blood drawn from 68 patients with a history of current or past therapy. Of those, 57 percent had resistance to at least one reverse transcriptase inhibitor or protease inhibitor. Resistance to AZT was found in 43 percent of patients, while resistance to 3TC was found in 15 percent of the sample. [*Abstract TuOrB280, "High Prevalence of Genotypic and Phenotypic Antiretroviral (ARV) Drug Resistant HIV-1 Strains among Patients Receiving ARV in Abidjan, Côte d'Ivoire," Christiane Adje, Oral Presentation, Tuesday, 11 July 2000, 14:00 (8:00 AM EDT)*]
- **Women in Côte d'Ivoire May Need Different Treatment Guidelines:** While the immune systems of all of the patients accessing the UNAIDS/Ministry of Health Initiative in Abidjan were severely compromised, women may need treatment at higher CD4+ immune cell levels than men. The study of 1,864 patients, by Mireille Kalou, M.D., found that women had a significantly higher median number of CD4+ cells than men (183 for women and 126 for men), in spite of the fact that average

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<sup>1</sup> Resistance found through phenotypic testing, which measures the actual sensitivity of a patient's HIV to particular drugs by isolating virus from the patient and measuring its growth against common HIV medications.



viral load in both groups was similar. This finding is significant because it raises the possibility of initiating antiretroviral therapy differently for men and women.

***[Abstract TuPeA3109, “CD4+T-cell counts, HIV-1 RNA Viral Load (VL), and Viral Phenotypes among Drug-Naïve HIV-infected Adults Seeking Care through the UNAIDS/Ministry of Health Drug-Access Initiative (DAI) in Abidjan, Côte d’Ivoire,” Mireille Kalou, M.D., Poster Presentation, Tuesday, 11 July 2000, 11:15 (5:15 AM EDT)]***

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